THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CAMDEN VICINAGE

In re: VALSARTAN, LOSARTAN, and IRBESARTAN: PRODUCTS LIABILITY LITIGATION:

Master Docket No. 19-2875 (RBK/SAK)

Order VACATING opinion and order in ECF Docs. 2581 and 2582 ONLY as to Expert Report of Timothy Anderson; and New Order re Liability Expert Report of Timothy Anderson

This Document Applies to All Actions

KUGLER, United States District Judge:

BEFORE THE COURT in this multidistrict litigation ("MDL") is a motion by Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries, Ltd., Actavis LLC, and Actavis Pharma, Inc. [collectively "Teva" or "defendants"] seeking to amend / correct this Court's Opinion (Doc. No. 2581) and Order (Doc. No. 2582) as to the expert report of Timothy Anderson;

THE COURT RECOGNIZING that Its Opinion/Order (Docs. 2581, 2582) had relied mistakenly on Mr. Anderson's expert report on class certification rather than on his expert report on liability;

THE COURT APPRECIATING Teva's alert to Its mistake; and

THE COURT HAVING REVIEWED Mr. Anderson's expert report on liability and Teva's suggestions as to paragraphs to preclude in this report, and without a hearing in accordance with *Loc.R.* 78.1 (b), for the reasons stated below, and for good cause shown,

IT IS HEREBY ORDERED:

ONLY that portion of this Court's Opinion at Doc. No. 2581 and ONLY that portion of this Court's Order at Doc. No. 2582 specifically concerning Timothy Anderson's expert report on class certification dated 12 Jan 2022 are VACATED;

IT IS FURTHER ORDERED:

plaintiffs' motion, Doc. No. 2297, to preclude Timothy Anderson's expert report on liability dated 19 Dec 2022 **IS GRANTED IN PART AND DENIED IN PART**;

IT IS FURTHER ORDERED:

The opinions in the following paragraphs of Anderson's expert report on liability dated 19 Dec 2022 are **PRECLUDED**:

 $\P \P 20 - 22$ for legal assessment that Teva could not have reasonably foreseen is not helpful to the factfinder, as stated in *Federal Rule of Evidence* ["*FRE"*] 702;

 $\P \P 25 - 27$ for implication that absence of FDA behavior constitutes legal determination of "not adulterated";

 $\P \P_{33} - 34$ for legal assessment that Teva acted as a reasonably prudent and reasonably compliant manufacturer is not helpful to the factfinder, as stated in *Federal Rule of Evidence 702*;

¶49 for assuming that FDA's inaction regarding ZHPs process change implied FDA's approval as to Teva's not changing its DMF filings;

¶91 for irrelevance in citing a USP monograph published more recently than during the relevant period;

 \P 104 – 105 for irrelevance in citing USP chapters, monographs, and revisions published more recently than during the relevant period;

¶144 for irrelevance in referring to and citing FDA's 2021 Guidance for setting specific limitations on nitrosamine impurities as outside the relevant period;

 \P ¶221 – 222 for a legal assessment of the meaning of the FDA's absence of statement, and constituting pure *ipse dixit*; and

IT IS FURTHER ORDERED:

the opinions in the rest and remainder of Anderson's liability report dated 19 Dec 2022 are **NOT PRECLUDED.**

Dated: 23 January 2024 /s Robert B. Kugler

The Honorable Robert B. Kugler United States District Judge